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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,213	07/24/2003	Emilio Barbera-Guillem	26983-133	9675

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	**PAPER NUMBER**
1644	

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06/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,213	BARBERA-GUILLEM ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 18-48* is/are pending in the application.

4a) Of the above claim(s) *19,25,28,35 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,18,20-24,26,27,29-34,36-39 and 41-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election with traverse of the species CD19 and site directed in the reply filed on 11/13/06 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons. Regarding applicants comments, the aformentioned species are distinct for the reasons elaborated in the previous Office Action. It would place an undue burden upon the Examiner to search additional species.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 19,25,28,35,40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/13/06.

3. Applicant's election of depletes B cells and pharmaceutically acceptable carrier in the reply filed on 4/10/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 1,18,20-24,26,27,29-34,36-39,41-48 are under consideration.

5. Applicant is required to update the status of all US patent applications disclosed in the instant application.

6. Applicant states that this application is a continuation or divisional application of the prior-filed application. A continuation or divisional application cannot include new matter. Applicant is required to change the relationship (continuation or divisional application) to continuation-in-part because this application contains the following matter not disclosed in the prior-filed application.

There is no support in the parent applications for claim 1, lines 2-3 (or said limitation in claims 26,33,38). Regarding applicants comments, the specification, page 13 contains other limitations regarding the limitation under consideration such that the

absence of said limitations broadens the scope of the claimed invention such that it lacks support in the parent applications. There is no support in the parent applications for the recitation of "a determinant expressed only by B cells and not by immune cells other than B cells" in claims 1,26,33,38. There is no support in the parent applications for claim 1, last three lines or said limitation in claims 26,33. There is no support in the parent applications for claims 22,23,30,31,37,43,44,48. Regarding applicants comments, the specification, page 14 contains other limitations regarding the limitation under consideration such that the absence of said limitations broadens the scope of the claimed invention such that it lacks support in the parent applications. There is no support in the parent applications for claim 38 or claim 45, lines 2-3.

7. Claims 1,18,20-24,26,27,29-34,36-39,41-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of claimed invention.

The claims recite use of an antibody that binds CD19, wherein said claims encompass use of antibody which binds CD19 from any animal species. It is unclear as to what species of CD19 were known in the art other than murine or human. The identity of CD19 from unknown species is unpredictable. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli

Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

8. Regarding the application of prior art and priority to parent applications, for the same reason that claims lack written description or description in the parent applications, they are not entitled to priority to the parent application to which priority is claimed.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1,18,20-24,33,34,36-39,41-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et al. (EP 0332865).
According to the specification, page 3, last paragraph , the pro-MS immune response recited in the claims causes MS and is found in MS patients. In addition, said response is also disclosed in the specification as responsible for clinical manifestations of progressive MS (see page 4, last paragraph and page 14, last paragraph). Meyer et al. teach treatment of progressive MS with the antiB cell antibody Lym-1 in a pharmaceutically acceptable carrier (see page 3) via injection (see Example 9) . Meyer et al. disclose that said antibody is used to deplete mature B cells (see page 3, third paragraph, wherein the antibody does not recognize stem cells, thus allowing for a later repopulation of B-lymphocytes (aka the mature B cells have been depleted)). Depletion of B cells would result in reduction of responses mediated by B cells.

11. Claims 45,47,48 are rejected under 35 U.S.C. 102(b) or 102(e) as being anticipated by Aruffo et al (US Pat. No. 6,051,228).
According to the specification, page 3, last paragraph , the pro-MS immune response recited in the claims causes MS and is found in MS patients. Aruffo et al. teach a method of treating the autoimmune disease multiple sclerosis (MS) by administering a chimeric antibody to the CD40 antigen (see entire document, e.g., columns 21-22 and in particular column 21 at lines 25-31). Aruffo et al. teach that CD40 is a B cell determinant

expressed on B cells (e.g., column 1 at lines 14-22, and that antibody to CD40 depletes B cells when administered in vivo (e.g., column 9 at lines 46 and column 12 at lines 37-55). Aruffo et al. teach that the anti-CD40 antibody is administered as a composition comprising a pharmaceutically acceptable carrier (e.g., columns 21 to 22). Aruffo et al. teach that the compositions comprising the anti-CD40 antibody may be administered intravenously, or by other parenteral routes (e.g., column 21 at lines 32-36). Depleting B cells with an anti-CD40 antibody in vivo would also inherently deplete mature and memory B cells, CD19÷sTn+ B cells, CD19+CD21+sTn+ B cells and CD19+CD5÷sTn+ B cells, including nonmalignant B cells. Finally, administering an anti-CD40 antibody to treat an individual suffering from MS would require that the antibody be administered in an amount effective to reduce the inflammation underlying the clinical manifestations of MS.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1,18,20-24,33,34,36-39,41-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et al. (EP 0332865) in view of Pesando (WO 91/13974) and Aruffo et al (US Pat. No. 6,051,228).

According to the specification, page 3, last paragraph , the pro-MS immune response recited in the claims causes MS and is found in MS patients. In addition, said response is also disclosed in the specification as responsible for clinical manifestations of progressive MS (see page 4, last paragraph and page 14, last paragraph). Meyer et al. teach treatment of progressive MS with the antiB cell antibody Lym-1 in a pharmaceutically acceptable carrier (see page 3) via injection (see Example 9) . Meyer et al. disclose that said antibody is used to deplete mature B cells (see page 3, third paragraph, wherein the antibody does not recognize stem cells, thus allowing for a later repopulation of B-lymphocytes (aka the mature B cells have been depleted)). Depletion of B cells would result in reduction of responses mediated by B cells. Meyer et al. does not disclose use of antiCD19 antibody in said method. Pesando discloses use of antiCD19 antibodies (which bind CD19 positive B cells) to treat autoimmune diseases (see page 4, penultimate paragraph). Aruffo et al. teach a method of treating the autoimmune disease multiple sclerosis (MS) by administering a chimeric antibody to the CD40 antigen (see entire document, e.g., columns 21-22 and in particular column 21 at lines 25-31). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Meyer et al. teach the claimed methods except for use of antiCD19 antibody whilst Pesando discloses use of antiCD19 antibodies to treat autoimmune diseases. One of ordinary skill in the art would have been motivated to do the aformentioned because Pesando discloses use of antiCD19 antibodies to treat autoimmune diseases whilst Aruffo et al. disclose that MS is an autoimmune disease.

14. Claims 20,26,27,29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et al. (EP 0332865) in view of Pesando (WO 91/13974) and Aruffo et al (US Pat. No. 6,051,228) as applied to claims 1,18,20-24,33,34,36-39,41-48 above, and further in view of Turk et al.

The previous rejection renders obvious the claimed invention except for delivery of the antibody into an access that directly supplies central nervous system tissue. Turk et al. disclose intrathecal (aka delivery of the antibody into an access that directly supplies central nervous system tissue) delivery of antibody for treatment of MS (see column 6, penultimate paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the previous rejection renders obvious the claimed invention except for delivery of the antibody into an access that directly supplies central nervous system tissue whilst Turk et al. disclose intrathecal (aka delivery of the antibody into an access that directly supplies central nervous system tissue) delivery of antibody for treatment of MS.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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